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(54) Title: DUAL PHASE ORAL COMPOSITIONS CONTAINING A BASIC PHASE AND AN ACIDIC PHASE

(57) Abstract

The present invention relates to an oral formulation contained in physically separated compartments of a suitable dispenser, comprising a first oral composition comprising from about 0.5 % to about 50 % of an alkali metal bicarbonate salt, from about 0.5 % to about 30 % of propylene glycol, from about 20 % to about 99 % of one or more aqueous carriers, and a second oral composition comprising from about 0.5 % to about 20 % of an acidic compound and from about 80 % to about 99.5 % of one or more aqueous carriers.

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DUAL PHASE ORAL COMPOSITIONS CONTAINING A BASIC PHASE AND AN ACIDIC PHASE

BACKGROUND OF THE INVENTION

The present invention relates to two phase oral formulations which contain ingredients when upon contact with each other neutralize and produce an effervescent effect. This invention comprises a basic phase which comprises an alkali metal bicarbonate salt and propylene glycol and an acidic phase which comprises an acidic compound. Effervescent dentifrice and mouthrinse compositions have been recognized as having desirable and advantageous aesthetic properties.

Oral care products consisting of separated first and second compositions, each composition containing reactive components, which when brought together effervescence are already known in the art. U.S. Patent 3,729,553, issued April 24, 1973, to Gold et al., discloses an effervescing mouthwash composition. Effervescing toothpastes are disclosed in U.S. Patent 4,487,757, issued December 11, 1984, to Kiozpeoplou, and in WO 95/02392, published January 26, 1995.

The present inventors have discovered that an effervescent oral composition can be developed with improved sensory attributes. By adding propylene glycol to the oral compositions containing an alkali metal bicarbonate salt, the brushing experience provides a lighter foam, more enhanced cooling, and a clean teeth feeling. Therefore, it is an object of the present invention to provide stable oral formulations comprising two oral compositions which are contained in physically separated compartments. The first oral composition comprises an alkali metal bicarbonate salt and propylene glycol while the second oral composition comprises an acidic compound. It is also an object of the present invention to provide a first oral composition comprising an alkali metal bicarbonate salt, propylene glycol, polyphosphate, an alkali metal carbonate salt, calcium peroxide, and an abrasive polishing material and a second oral composition comprising citric acid and a fluoride ion source. It is also an object of the present invention to provide oral formulations with antitartar activity through the use of tartar control agents.

These and other objects of the present invention will become readily apparent from the detailed description which follows.

All percentages and ratios used herein are by weight of the specific oral composition and not of the overall oral formulation that is delivered, unless otherwise specified. All measurements are made at 25° C, unless otherwise specified.

SUMMARY OF THE INVENTION

The present invention relates to an oral formulation contained in physically separated compartments of a suitable dispenser, comprising a first oral composition comprising from about 0.5% to about 50% of an alkali metal bicarbonate salt, from about 0.5% to about 30% of propylene glycol, from about 20% to about 99% of one or more aqueous carriers; and a second oral composition comprising from about 0.5% to about 20% of an acidic compound and from about 80% to about 99.5% of one or more aqueous carriers.

DETAILED DESCRIPTION OF THE INVENTION

The oral formulation of the present invention may be in the form of a toothpaste, dentifrice or mouthrinse. The term "oral formulation" as used herein means the total dentifrice or mouthrinse that is delivered to the oral surfaces. The oral formulation is a combination of the two or more dentifrice or mouthrinse compositions. The oral formulation is a product, which in the ordinary course of usage, is not intentionally swallowed for purposes of systemic administration of particular therapeutic agents, but is rather retained in the oral cavity for a time sufficient to contact substantially all of the dental surfaces and/or oral tissues for purposes of oral activity.

The term "dentifrice", as used herein, means paste, gel, or liquid formulations unless otherwise specified. The dentifrice composition may be in any desired form, such as deep striped, surface striped, multilayered, having the gel surrounding the paste, or any combination thereof. Each dentifrice composition will be contained in a physically separated compartment of a dispenser and dispensed side-by-side.

The term "dispenser", as used herein, means any pump, tube, bottle, or container suitable for dispensing a dentifrice or mouthrinse.

The term "aqueous carrier" as used herein means any safe and effective materials for use in the compositions of the present invention. Such materials include abrasive polishing materials, buffering agents, calcium peroxide, thickening materials, humectants, water, surfactants, titanium dioxide, flavor system, coolants, sweetening agents, xylitol, coloring agents, antimicrobial agents, and mixtures thereof.

The present compositions comprise essential components, as well as optional components. The essential and optional components of the compositions of the present invention are described in the following paragraphs.

Alkali Metal Bicarbonate Salt

The first oral composition of the present invention will include an alkali metal bicarbonate salt. Sodium bicarbonate, also known as baking soda, is the preferred alkali

metal bicarbonate salt. The present composition will contain from about 0.5% to about 50%, preferably from about 2% to about 20%, more preferably from about 5% to about 18%, and most preferably from about 10% to about 15% of an alkali metal bicarbonate salt, by weight of the oral composition.

Propylene Glycol

The first oral composition of the present invention also comprises propylene glycol. The propylene glycol is suitable for use on the skin and mucosal surfaces such as in the oral cavity. The first oral composition will contain from about 0.5% to about 30%, preferably from about 1% to about 20%, and more preferably from about 2% to about 15% of propylene glycol, by weight of the oral composition.

Acidic Compound

The second oral composition of the present invention incorporates an acidic compound. The acidic compound may be organic or inorganic. The acidic compound may be any material which will be a proton donor that is capable of neutralizing bicarbonate. Acidic compounds suitable for use include carboxylic acids, phosphoric acids, alpha-hydroxy acids, sulfonic acids, and mixture thereof. Specific acids include citric acid, malic acid, alginic acid, succinic acid, lactic acid, tartaric acid, glycolic acid, adipic acid, potassium bitartrate acid, acid sodium citrate, phosphoric acid, boric acid, and acid phosphate and pyrophosphate salts. A blend of acids are preferred. Citric acid and malic acid are preferred. Acid anhydrides and acid salts of the above acids may also be used. Suitable salts include mono or disodium salts of citric acid, mono sodium salts of malic acid, and mixtures thereof. The second oral composition will contain from about 0.5% to about 20%, preferably from about 1% to about 15%, and more preferably from about 4% to about 12% of an acidic compound, by weight of the oral composition.

Fluoride Ion Source

The first and/or second oral compositions of the present invention may incorporate a soluble fluoride ion source capable of providing free fluoride ions. Preferred soluble fluoride ion sources include sodium fluoride, stannous fluoride, indium fluoride, and sodium monofluorophosphate. Sodium fluoride is the most preferred soluble fluoride ion source. Norris et al., U.S. Patent 2,946,725, issued July 26, 1960, and Widder et al., U.S. Patent 3,678,154 issued July 18, 1972, disclose such fluoride ion sources as well as others. Both patents are incorporated herein by reference in their entirety. If the fluoride ion source is present in the second dentifrice composition and an abrasive polishing material is also present, it is preferred that the composition additionally comprise a material like mineral oil. The fluoride ion source should be

capable of providing from about 50 ppm to about 3500 ppm, and preferably from about 500 ppm to about 3000 ppm of free fluoride ions.

Tartar Control Agents

The present invention may include a tartar control agent. The tartar control agent may be present in the first or second oral compositions or both compositions. The tartar control agent may be any materials known to be effective in reducing calcium phosphate mineral deposition related to calculus formation. The preferred tartar control agent is selected from the group consisting of a polyphosphate source, tripolyphosphate source, a pyrophosphate salt, and mixtures thereof.

The pyrophosphate salts useful in the present compositions include the di and tetra alkali metal pyrophosphate salts, and mixtures thereof. Disodium dihydrogen pyrophosphate ($Na_2H_2P_2O_7$), tetrasodium pyrophosphate ($Na_4P_2O_7$), and tetrapotassium pyrophosphate ($K_4P_2O_7$) in their unhydrated as well as hydrated forms are the preferred species. In compositions of the present invention, the pyrophosphate salt may be present in one of three ways: predominately dissolved, predominately undissolved, or a mixture of dissolved and undissolved pyrophosphate.

Compositions comprising predominately dissolved pyrophosphate refer to compositions where at least one pyrophosphate ion source is in an amount sufficient to provide at least about 1.0% free pyrophosphate ions. Compositions comprising pyrophosphate typically containing from about 1% to about 15%, preferably from about 2% to about 10%, and most preferably from about 2% to about 8%, by weight of the composition. The pyrophosphate salts are described in U.S. Patent 4,515,772, issued May 7, 1985, and 4,885,155, issued December 5, 1989, both to Parran et al., incorporated herein by reference in their entirety, as well as the references disclosed therein.

The present invention may include a polyphosphate source. A polyphosphate is generally understood to consist of two or more phosphate molecules arranged primarily in a linear configuration, although some cyclic derivatives may be present. The inorganic polyphosphate salts desired include sodium tripolyphosphate, tetrapolyphosphate, and hexametaphosphate, among others. Polyphosphates larger than tetrapolyphosphate usually occur as amorphous glassy materials. Preferred are polyphosphates manufactured by FMC Corporation which are commercially known as Sodaphos ($n\approx6$), Hexaphos ($n\approx13$), and Glass H ($n\approx21$). The polyphosphate source will typically comprise from about 0.5% to about 20%, preferably from about 4% to about 15%, more preferably from about 6% to about 10%, and most preferably from about 7% to about 9%, by weight of the oral composition.

The phosphate sources are described in more detail in Kirk & Othmer, *Encyclopedia of Chemical Technology*, Fourth Edition, Volume 18, Wiley-Interscience Publishers (1996), pages 685-707, incorporated herein by reference in its entirety, including all references incorporated into Kirk & Othmer. Optional agents to be used in place of or in combination with the polyphosphate or pyrophosphate salt include such materials known to be effective in reducing calcium phosphate mineral deposition related to calculus formation. Agents included are synthetic anionic polymers [including polyacrylates and copolymers of maleic anhydride or acid and methyl vinyl ether (e.g., Gantrez), as described, for example, in U.S. Patent 4,627,977, to Gaffar et al., the disclosure of which is incorporated herein by reference in its entirety; as well as, e.g., polyamino propoane sulfonic acid (AMPS)], zinc citrate trihydrate, diphosphonates (e.g., EHDP; AHP), polypeptides (such as polyaspartic and polyglutamic acids), and mixtures thereof.

Aqueous Carriers

In preparing the present compositions, it is desirable to add one or more aqueous carriers to the oral compositions. Such materials are well known in the art and are readily chosen by one skilled in the art based on the physical and aesthetic properties desired for the compositions being prepared. Aqueous carriers typically comprise from about 10% to about 99%, preferably from about 50% to about 98%, and more preferably from about 60% to about 95%, by weight of the oral composition.

Abrasive Polishing Materials

An abrasive polishing material may also be included in one or both of the dentifrice compositions. The abrasive polishing material contemplated for use in the compositions of the present invention can be any material which does not excessively abrade dentin. Typical abrasive polishing materials include silicas including gels and precipitates; aluminas; phosphates including orthophosphates, polymetaphosphates, and insoluble pyrophosphates; and mixtures thereof. Silica dental abrasives of various types are preferred because of their unique benefits of exceptional dental cleaning and polishing performance without unduly abrading tooth enamel or dentine. The silica abrasive polishing materials herein, as well as other abrasives, generally have an average particle size ranging between about 0.1 to about 30 microns, and preferably from about 5 to about 15 microns. The abrasive can be precipitated silica or silica gels such as the silica xerogels described in Pader et al., U.S. Patent 3,538,230, issued Mar. 2, 1970, and DiGiulio, U.S. Patent 3,862,307, issued Jan. 21, 1975, both incorporated herein by reference. Preferred are the precipitated silica materials such as those marketed by the J. M. Huber Corporation under the trade name, "Zeodent", particularly the silica carrying

the designation "Zeodent 119". The types of silica dental abrasives useful in the toothpastes of the present invention are described in more detail in Wason, U.S. Patent 4,340,583, issued July 29, 1982, and in Rice, U.S. Patent 5,589,160, issued December 31, 1996, incorporated herein by reference. Silica abrasives described in U.S. patent applications, 08/434,147 and 08/434,154, both filed May 2, 1995, are also herein incorporated by reference. The abrasive in the toothpaste compositions described herein is generally present at a level of from about 6% to about 70% by weight of the composition. Preferably, toothpastes contain from about 10% to about 50% of abrasive, by weight of the dentifrice composition.

Calcium Peroxide

The present invention may include calcium peroxide in the dentifrice compositions. The following amounts represent the amount of peroxide raw material, although the peroxide source may contain ingredients other than the peroxide raw material. The present composition may contain from about 0.01% to about 10%, preferably from about 0.1% to about 5%, more preferably from about 0.2% to about 3%, and most preferably from about 0.3% to about 0.8% of a peroxide source, by weight of the oral composition.

Buffering Agent

The oral compositions may each contain a buffering agent. Buffering agents, as used herein, refer to agents that can be used to adjust the pH of the compositions. In the first oral composition, the pH is adjusted to a range of from about pH 8.0 to about pH 10.5. Preferably the pH is from about pH 8.0 to about pH 9.5 and more preferably from pH 8.2 to about pH 9.0. The buffering agents suitable include alkali metal hydroxides, carbonates, sesquicarbonates, borates, silicates, phosphates, imidazole, and mixtures thereof. Specific buffering agents include monosodium phosphate, trisodium phosphate, sodium hydroxide, potassium hydroxide, alkali metal carbonate salts, sodium carbonate, imidazole, and pyrophosphate salts. In the second oral composition, the pH is adjusted to a range of from about pH 1.5 to about pH 5.5. Preferably the pH is from about pH 1.5 to about pH 4.0 and more preferably from about pH 2.0 to about pH 3.5. Suitable buffering agents for the second oral composition include sodium acid pyrophosphate, sodium citrate, and sodium malate. Buffering agents are used at a level of from about 0.1% to about 30%, preferably from about 1% to about 10%, and more preferably from about 1.5% to about 3%, by weight of the oral composition.

Additional Aqueous Carriers

The present invention compositions in the form of toothpastes, typically contain some thickening material or binders to provide a desirable consistency. Preferred

thickening agents are carboxyvinyl polymers, carrageenan, hydroxyethyl cellulose, and water soluble salts of cellulose ethers such as sodium carboxymethylcellulose and sodium hydroxyethyl cellulose. Natural gums such as gum karaya, xanthan gum, gum arabic, and gum tragacanth can also be used. Colloidal magnesium aluminum silicate or finely divided silica can be used as part of the thickening agent to further improve texture. Thickening agents can be used in an of amount from about 0.1% to about 15%, by weight of the oral composition.

Another optional component of the oral compositions desired herein is a humectant. The humectant serves to keep toothpaste compositions from hardening upon exposure to air and certain humectants can also impart desirable sweetness of flavor to toothpaste compositions. Suitable humectants for use in the invention include glycerin, sorbitol, polyethylene glycol, polyoxyethylene, and other edible polyhydric alcohols. The polyethylene glycol or polyoxyethylene may have a molecular weight of from about 200 to about 7000. The humectant generally comprises from about 0% to 70%, and preferably from about 15% to 55%, by weight of the oral composition.

Water employed in the preparation of commercially suitable oral compositions should preferably be of low ion content and free of organic impurities. In the first or second oral compositions, water will generally comprise from about 5% to about 70%, and preferably from about 10% to about 50%, by weight of the composition herein. Alternatively, the dentifrice composition may comprise a lower level of water, generally from about 5% to about 20%, preferably from about 7% to about 14%, and more preferably from about 7% to about 12%, by weight of the dentifrice composition. The lower level of water is preferred in compositions comprising polyphosphates. The amounts of water include the free water which is added plus that which is introduced with other materials, such as with sorbitol, silica, surfactant solutions, and/or color solutions.

The present compositions may also comprise surfactants, also commonly referred to as sudsing agents. Suitable surfactants are those which are reasonably stable and foam throughout a wide pH range. The surfactant may be anionic, nonionic, amphoteric, zwitterionic, cationic, or mixtures thereof. Anionic surfactants useful herein include the water-soluble salts of alkyl sulfates having from 8 to 20 carbon atoms in the alkyl radical (e.g., sodium alkyl sulfate). Many suitable anionic surfactants are disclosed by Agricola et al., U.S. Patent 3,959,458, issued May 25, 1976, incorporated herein in its entirety by reference. Nonionic surfactants which can be used in the compositions of the present invention can be broadly defined as compounds produced by the condensation of alkylene oxide groups (hydrophilic in nature) with an organic hydrophobic compound

which may be aliphatic or alkyl-aromatic in nature. Examples of suitable nonionic surfactants include poloxamers (sold under trade name Pluronic), polyoxyethylene, polyoxyethylene sorbitan esters (sold under trade name Tweens), and mixtures of such materials. The amphoteric surfactants useful in the present invention can be broadly described as derivatives of aliphatic secondary and tertiary amines in which the aliphatic radical can be a straight chain or branched and wherein one of the aliphatic substituents contains from about 8 to about 18 carbon atoms and one contains an anionic water-solubilizing group, e.g., carboxylate, sulfonate, sulfate, phosphate, or phosphonate. Other suitable amphoteric surfactants are betaines, specifically cocamidopropyl betaine. Many of these suitable surfactants are disclosed by Gieske et al., U.S. Patent 4,051,234, issued September 27, 1977, incorporated herein by reference in its entirety. The present composition typically comprises one or more surfactants each at a level of from about 0.25% to about 12%, preferably from about 0.5% to about 8%, and most preferably from about 1% to about 6%, by weight of the composition.

Titanium dioxide may also be added to the present composition. Titanium dioxide is a white powder which adds opacity to the compositions. Titanium dioxide generally comprises from about 0.25% to about 5%, by weight of the composition.

Coloring agents may also be added to the present composition. The coloring agent may be in the form of an aqueous solution, preferably 1% coloring agent in a solution of water. Color solutions generally comprise from about 0.01% to about 5%, by weight of the composition.

A flavor system can also be added to the compositions. Suitable flavoring components include oil of wintergreen, oil of peppermint, oil of spearmint, clove bud oil, menthol, anethole, methyl salicylate, eucalyptol, cassia, 1-menthyl acetate, sage, eugenol, parsley oil, oxanone, alpha-irisone, marjoram, lemon, orange, cranberry, propenyl guaethol, cinnamon, vanillin, ethyl vanillin, heliotropine, 4-cis-heptenal, diacetyl, methyl-para-tert-butyl phenyl acetate, and mixtures thereof. A flavor system is generally used in the compositions at levels of from about 0.001% to about 5%, by weight of the composition.

Coolants may also be part of the flavor system or added separately to the composition. Preferred coolants in the present compositions are the paramenthan carboxyamide agents such as N-ethyl-p-menthan-3-carboxamide (known commercially as "WS-3"), menthol, 3-1-menthoxypropane-1,2-diol ("TK-10"), menthone glycerol acetal ("MGA"), menthyl lactate, and mixtures thereof. A coolant is generally used in the compositions at levels of from about 0.001% to about 5%, by weight of the composition.

The present invention may also include xylitol. Xylitol is a sugar alcohol that is used as a sweetener and humectant. Xylitol may provide a therapeutic effect, such as an antibacterial or anticaries effect. The present compositions typically comprise xylitol at a level from about 0.01% to about 25%, preferably from about 3% to about 15%, more preferably from about 5% to about 12%, and most preferably from about 9% to about 11%, by weight of the total composition. Alternatively, if xylitol is used as a sweetener, it may be present at a lower level, such as from about 0.005% to about 5%, by weight of the oral composition.

Sweetening agents can be added to the compositions. These include saccharin, dextrose, sucrose, lactose, maltose, levulose, aspartame, sodium cyclamate, D-tryptophan, dihydrochalcones, acesulfame, and mixtures thereof. Various coloring agents may also be incorporated in the present invention. Sweetening agents and coloring agents are generally used in toothpastes at levels of from about 0.005% to about 5%, by weight of the composition.

The present invention may also include other agents, such as antimicrobial agents. Included among such agents are water insoluble non-cationic antimicrobial agents and water soluble antimicrobials, such as quaternary ammonium salts and bis-biquanide salts, among others. Triclosan monophosphate is an additional water soluble antimicrobial agent. Other compounds are bis[4-(R-amino)-1-pyridinium] alkanes as disclosed in U.S. Patent 4,206,215, issued June 3, 1980, to Bailey, incorporated herein by reference. Stannous salts such as stannous pyrophosphate and stannous gluconate and other antimicrobials such as copper bisglycinate, copper glycinate, zinc citrate, and zinc lactate may also be included. Also useful are enzymes, including endoglycosidase, papain, dextranase, mutanase, and mixtures thereof. Such agents are disclosed in U.S. Patent 2,946,725, Jul. 26, 1960, to Norris et al. and in U.S. Patent 4,051,234, September. 27, 1977 to Gieske et al., incorporated herein by reference. Specific antimicrobial agents include chlorhexidine, triclosan, triclosan monophosphate, and flavor oils such as thymol. Triclosan and other agents of this type are disclosed in Parran, Jr. et al., U.S. Patent 5,015,466, issued May 14, 1991, and U.S. Patent 4,894,220, Jan. 16, 1990 to Nabi et al., incorporated herein by reference. These agents may be present at levels of from about 0.01% to about 1.5%, by weight of the oral composition.

The oral formulation may be a dentifrice or mouthrinse. If the oral formulation is a dentifrice, the first and second dentifrice compositions will be physically separated in a dentifrice dispenser. The dentifrice compositions may be a paste, gel, or any configuration or combination thereof. It is preferred that the first dentifrice composition be a paste and the second dentifrice composition be a gel. The dispenser may be a tube,

pump, or any other container suitable for dispensing toothpaste. Dual compartment packages suitable for this purpose are described in U.S. Patent 4,528,180, issued July 9, 1985; U.S. Patent 4,687,663, issued August 18, 1987; and 4,849,213, issued July 18, 1989, all to Shaeffer, all incorporated herein in their entirety. The dispenser will deliver approximately equal amounts of each dentifrice composition through an opening. The compositions may intermix once dispensed. Alternatively, the oral formulation may be delivered from a kit containing two separate dispensers which are used to deliver two dentifrice compositions that are both used simultaneously.

Alternatively, the oral formulation may be a mouthrinse. Again, the first and second mouthrinse compositions will be physically separated until dispensed. Dual compartment packages suitable for this purpose are described in U.S. Patent 3,729,553, issued April 24, 1973, U.S. Patent 5,252,312, issued October 12, 1993, U.S. Patent 5,289,950, issued March 1, 1994, and 5,392,947, issued February 28, 1995, all incorporated herein in their entirety.

Once the two compositions are intermixed, the oral formulation will produce an effervescent effect. The pH of this intermixed composition will be from about pH 6.0 to about pH 7.5 and preferably from about pH 6.5 to about pH 7.0. To achieve this pH neutralization, the weight ratio of bicarbonate to acidic compound is generally from about 40:1 to about 1:2, preferably from about 10:1 to about 1:2, and more preferably from about 2:1 to 1:1.

The present compositions can be in the form of a mouth rinse or liquid dentifrice where conventional mouth rinse components comprise the aqueous carriers of the present invention. Mouth rinses and liquid dentifrices generally comprise from about 20:1 to about 2:1 of a water ethyl alcohol or alcohol free solution, and preferably other ingredients such as flavors, sweeteners, and humectants as those mentioned above. The humectants, such as glycerin and sorbitol, give a moist feel to the mouth. Generally on a weight basis, the mouth rinses and liquid dentifrices of the present invention comprise from about 0% to about 60% ethyl alcohol, from about 0% to about 20% humectant, from about 0% to about 0.5% sweetening agent, from about 0% to about 0.3% of a flavoring system, and the balance water.

Method of Treatment

The method of treatment herein comprises contacting the dental enamel surfaces in the mouth with the oral compositions according to the present invention.

Examples & Method of Manufacturing

The following examples further describe and demonstrate embodiments within the scope of the present invention. These examples are given solely for the purpose of

illustration and are not to be construed as limitations of the present invention as many variations thereof are possible without departing from the spirit and scope.

EXAMPLE I

First Dentifrice Composition		Second Dentifrice Composition	
Ingredient	Wt. %	Ingredient	Wt. %
Carboxymethylcellulose	0.40	Color	0.30
Water	5.00	Water	26.52
Flavor	1.00	Flavor	1.00
Glycerin	33.40	Glycerin	9.00
Poloxamer 407	3.00	Sorbitol(c)	20.00
Propylene Glycol	8.50	Polyoxyethylene	1.00
Sodium Alkyl Sulfate(a)	4.00	Sodium Saccharin	0.35
Silica	20.50	Coolant	0.60
Sodium Carbonate	2.00	Mineral Oil	1.00
Sodium Saccharin	0.40	Sodium Fluoride	0.48
Sodium Bicarbonate	12.00	Citric Acid	10.00
Titanium Dioxide	1.00	Carboxymethylcellulose	0.50
Xanthan Gum	0.20	Xanthan Gum	0.25
Glass H Polyphosphate	4.00	Polyethylene Glycol	3.00
Polyethylene Glycol	3.00	Sodium Alkyl Sulfate(a)	6.00
Coolant	0.60	Silica	20.00
Polyoxyethylene	1.00		

(a) 27.9% solution

(c) 70% solution

EXAMPLE II

First Dentifrice Composition		Second Dentifrice Composition	
Ingredient	Wt. %	Ingredient	Wt. %
Carboxymethylcellulose	0.40	Color	0.30
Water	5.00	Water	26.52
Flavor	1.00	Flavor	1.00
Glycerin	34.40	Glycerin	11.25

Poloxamer 407	3.00	Sorbitol(c)	20.00
Propylene Glycol	8.50	Silica	20.00
Sodium Alkyl Sulfate(a)	4.00	Sodium Saccharin	0.35
Silica	20.50	Coolant	0.60
Sodium Carbonate	2.00	Mineral Oil	1.00
Sodium Saccharin	0.40	Sodium Fluoride	0.48
Sodium Bicarbonate	12.00	Phosphoric Acid	8.75
Titanium Dioxide	1.00	Carboxymethylcellulose	0.50
Xanthan Gum	0.20	Xanthan Gum	0.25
Glass H Polyphosphate	4.00	Polyethylene Glycol	3.00
Polyethylene Glycol	3.00	Sodium Alkyl Sulfate(a)	6.00
Coolant	0.60		

(a) 27.9% solution

(c) 70% solution

Examples I and II are made as follows. The first dentifrice compositions are prepared by adding the water and saccharin to a mixing vessel. Disperse the thickening agents, carboxymethyl cellulose and xanthan gum, in the glycerin. Add this mixture of dispersed thickening agents in glycerin to the mixing vessel and mix well. Add the flavor, coolant, Poloxamer, polyoxyethylene (if used), polyethylene glycol, propylene glycol, titanium dioxide, and sodium alkyl sulfate to the mixture and mix well. Next add the sodium carbonate and the silica. After mixing, add the sodium bicarbonate. Finally, add the polyphosphate. Continue stirring the mixture until homogeneous.

The second dentifrice compositions are prepared as follows. Add the water, saccharin, fluoride, sorbitol, mineral oil, polyethylene glycol, polyoxyethylene (if used), color, and acid to the mixing vessel. Disperse the thickening agents, carboxymethyl cellulose and xanthan gum, in the glycerin. Add this mixture of dispersed thickening agents in glycerin to the mixing vessel and mix well. Add the silica into the mixture and mix for at least 10 minutes. Finally, add the flavor, coolant, and sodium alkyl sulfate. Continue stirring the mixture until homogeneous.

EXAMPLE III

First Dentifrice Composition		Second Dentifrice Composition	
Ingredient	Wt. %	Ingredient	Wt. %
Carboxymethylcellulose	0.80	Color	0.30

Water	10.00	Water	30.00
Flavor	1.60	Flavor	1.30
Glycerin	8.00	Glycerin	40.00
Polyethylene Glycol	3.00	Poloxamer 407	20.00
Propylene Glycol	8.50	Malic Acid	8.00
Sodium Alkyl Sulfate(a)	4.00	Sodium Saccharin	0.40
Silica	20.00		
Sodium Carbonate	1.90		
Sodium Saccharin	0.40		
Sodium Bicarbonate	10.00		
Titanium Dioxide	1.00		
Sorbitol(c)	30.40		
Sodium Fluoride	0.40		

(a) 27.9% solution

(c) 70% solution

Example III is prepared as follows. The first dentifrice composition is prepared by adding the water, saccharin, and fluoride to a mixing vessel. Disperse the carboxymethyl cellulose in the glycerin and sorbitol. Add this mixture of dispersed thickening agents to the mixing vessel and mix well. Add the flavor, polyethylene glycol, propylene glycol, titanium dioxide, and sodium alkyl sulfate to the mixture and mix well. Next add the sodium carbonate and the silica. After mixing, add the sodium bicarbonate. Continue stirring the mixture until homogeneous.

The second dentifrice composition is prepared as follows. Add the water, saccharin, color, and acid to the mixing vessel. Add the glycerin and Poloxamer and mix until the Poloxamer melts. Finally, add the flavor and continue stirring the mixture until homogeneous.

EXAMPLE IV

First Mouthrinse Composition		Second Mouthrins Composition	
Ingredient	Wt. %	Ingredient	Wt. %
Glycerin	9.69	Glycerin	10.80
Water	65.00	Water	65.00
Saccharin	0.06	Saccharin	0.06
Flavor	0.20	Flavor	0.10

Propylene Glycol	5.00	Propylene Glycol	5.00
Sodium Carbonate	0.05	Color	0.04
Sodium Bicarbonate	5.00	Phosphoric Acid	4.00
Ethanol	15.00	Ethanol	15.00

Example IV is prepared as follows. Combining the water, saccharin, and color (if used) in a mixing vessel. Add the glycerin and propylene glycol. Next, add the flavor system and ethanol. Finally, add the sodium carbonate and bicarbonate for the first composition or the phosphoric acid for the second composition. Continue mixing each composition until homogeneous.

What is claimed is:

1. An oral formulation contained in physically separated compartments of a dispenser, comprising:
   a. a first oral composition comprising:
      (i) from 0.5% to 50% of an alkali metal bicarbonate salt;
      (ii) from 0.5% to 30% of propylene glycol;
      (iii) from 20% to 99% of one or more aqueous carriers; and
   b. a second oral composition comprising:
      (i) from 0.5% to 20% of an acidic compound; and
      (ii) from 80% to 99.5% of one or more aqueous carriers.

2. The oral formulation according to Claim 1 wherein the acidic compound of the second oral composition is selected from the group consisting of carboxylic acids, phosphoric acids, alpha-hydroxy acids, sulfonic acids, and mixtures thereof.

3. The oral formulation according to Claim 2 wherein the alkali metal bicarbonate salt of the first oral composition is sodium bicarbonate.

4. The oral formulation according to Claim 3 wherein the first oral composition further comprises from 50 ppm to 3500 ppm of free fluoride ions.

5. The oral formulation according to Claim 4 wherein the first oral composition further comprises an effective amount of one or more tartar control agents selected from the group consisting of polyphosphates, pyrophosphate salts, tripolyphosphates, and mixtures thereof.

6. The oral formulation according to Claim 4 wherein the first oral composition, second oral composition, or both oral compositions further comprise an effective amount of one or more antimicrobial agents selected from the group consisting of zinc salts, triclosan, chlorhexidine, cetyl pyridinium chloride, and mixtures thereof.

7. The oral formulation according to Claim 4 wherein the weight ratio of the alkali metal bicarbonate to the acidic compound is from 40:1 to 1:2.

8. The oral formulation according to Claim 7 wherein the pH of the first oral composition is from 1.5 to 5.5 and the pH of the second oral composition is from 8.0 to 10.5.

9. The oral formulation according to Claim 8 wherein the first oral composition in the form of a paste and the second oral composition in the form of a gel are dispensed side-by-side to give a striped appearance.

10. An oral formulation contained in physically separated compartments of a dispenser, comprising:

a. a first dentifrice composition comprising:

(i) from 0.5% to 50% of sodium bicarbonate;

(ii) from 0.5% to 30% of propylene glycol;

(iii) from 1% to 15% of a polyphosphate;

(iv) from 0.1% to 30% of an alkali metal carbonate salt:

(v) from 0.01% to 10% of calcium peroxide;

(vi) from 10% to 70% of an abrasive polishing material: and

(vii) from 10% to 85% of one or more aqueous carriers: wherein the first dentifrice composition has a total water

(viii) content of from 5% to 20%; and

b. a second dentifrice composition comprising:

(i) from 0.5% to 20% of citric acid;

(ii) a soluble fluoride source capable of providing from 50 ppm to 3500 ppm of free fluoride ions: and

(iii) from 80% to 99% of one or more aqueous carriers.

INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/US 98/04456

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61K7/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 599 525 A (D. HSU ET AL.) 4 February 1997 see claim 1; table 2	1
A	WO 95 02392 A (UNILEVER N.V., UNILEVER PLC) 26 January 1995 cited in the application see page 3, line 9; claim 1; example 4	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 June 1998	06/07/1998

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INTERNATIONAL SEARCH REPORT

information on patent family members

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